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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,637	11/14/2003	Robert J. Dunki-Jacobs	END-5240	2410
27777	7590 07/05/2006		EXAMINER	
PHILIP S. JOHNSON			JUNG, WILLIAM C	
JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA		ART UNIT	PAPER NUMBER	
	WICK, NJ 08933-7003		3768	
			DATE MAILED: 07/05/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
	10/713,637	DUNKI-JACOBS ET AL.			
Office Action Summary	Examiner	Art Unit			
	William Jung	3768			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1) Responsive to communication(s) filed on 22 M	lay 2006.				
	action is non-final.				
3) Since this application is in condition for allowa	this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4) Claim(s) 1-31 is/are pending in the application					
4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6)⊠ Claim(s) <u>1-31</u> is/are rejected.					
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or election requirement.					
Application Papers					
9)☐ The specification is objected to by the Examiner.					
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:					
1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the priority documents have been received in this National Stage					
application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.					
Attachment(s)					
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application (PTO-152)  6) Other:					

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#### **DETAILED ACTION**

## Response to Arguments

1. Applicant's arguments with respect to claims 1-31 have been considered but are moot in view of the new ground(s) of rejection.

# Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 3. Claims 12-27 are rejected under 35 U.S.C. 102(b) as being anticipated by *Kovacs et al* (US 5,833,603).

Kovacs et al anticipate disclose all claimed features in claims 12-27.

Claim 12: Kovacs et al disclose a system and method for detecting tissues comprising a capsule comprising a detector, a substance for associating with a target tissue where the substance is capable of being detected by the detector and a machine for verifying at least one of the detector and substance are suitable for use (col. 3, line 10 – col. 4, line 59; col. 6, lines 8-56). Kovacs et al disclose that the detected signals and analyzed mathematically and determined whether a particular tissue is present in the patient such as temporary implants, prosthesis, patient's organs and tissues (col. 3, lines 24-32).

Claims 13-18: Kovacs et al further disclose the method above where steps of verifying at least one component and concentration (amount of chemical or biochemical substance) of the physical properties of the tissue, cell, and biochemical components of region of interest.

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Although, Kovacs et al do not explicitly state that the detection substance is a monoclonal body, peptide, nanoparticle, mRNA and DNS corresponding to a generic monoclonal antibody, and liposome, these are inherent properties of biochemical composition of the tissues and cells (col. 6, lines 26-36).

Claims 19-23: Kovacs et al disclose that the biosensor detects energy spectra via optical or photosensor, which is used along with dye to acquire optical radiation. Although Kovacs et al do not explicitly state use or radioisotopes, the dye solution with radiation optical acquisition is inherent that the dye solution must be radioactive or radioisotopes (col. 1, lines 56-65; col. 4, lines 34-44; col. 5, lines 5-26).

Claims 24-27: Kovacs et al further discloses the method above where the sensor is a spectrophotometer acquiring multiple images of data from a region of interest with predetermine spectrum, wavelengths, and position to detect optical spectrum, i.e. spatial response pattern (col. 1,line 66 – col. 2, line 11).

### Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 1-11 and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Kovacs et al* in view of *Iddan et al* (US 5,604,531) and *Okada et al* (US 5,424,546).

Kovacs et al substantially anticipate all claimed features in claims 1-11 and 28-31.

Kovac et al disclose a system for detecting tissues comprising a capsule comprising a detector, a

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substance for associating with a target tissue where the substance is capable of being detected by the detector and a machine for verifying at least one of the detector and substance are suitable for use (col. 3, line 10 – col. 4, line 59; col. 6, lines 8-56). In addition, Kovacs et al disclose that the capsule includes multiple detectors, a radiation detector, magnetic detector, and single analyzer for each detector (col. 4, lines 35-44). Although Koyacs et al disclose implantation of the sensor device, Kovacs et al do not disclose that the capsule is a swallowable or that the capsule material is coated to allow the capsule to goes through the gastro-intestinal (GI) tract. However, Kovacs et al's deficiency is well known in the art where Iddan et al teaches a similar capsule detector where the device is swallowable and coated with material to allow the detector to pass through the GI tract (col. 1, lines 34-40; col. 3, line 8 – col. 5, line 6). In addition, neither Kovacs et al nor Iddan et al specifically disclose that detector pulse shaping device is in direct communication with a single channel analyzer configured to analyze the voltage output. This particular feature is well known in the art as evident by Okada et al. Okada et al teach that an endoscopic or catheter with a detector includes single channel analyzer that counts the detected photons, i.e. voltage output from the pulse shaping device (col. 10, lines 13-29). Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply Kovacs et al's teachings as described above with Iddan et al's device designed to be swallow through the GI tract and Okada et al's single channel analyzer to achieve the claimed invention.

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### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Jung, Ph.D. whose telephone number is 571-272-4739. The examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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